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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,863	12/16/2003	Robert Emmett Atkinson	AEWI-1	5348

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/736,863

Applicant(s)

ATKINSON ET AL.

Examiner

Michael Kahelin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-32, 34-38 and 40-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-32, 34-38 and 40-49 is/are rejected.
- 7) ☒ Claim(s) 31 and 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09032004;10042005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 31 and 37 are objected to because of the following informalities: "in" should read "is". Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 29-32, 34-38 and 40-49 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Balat et al. (US 4,258,724, hereinafter "Balat"). Balat discloses the essential features of the claimed invention including the following:

6. In regards to claims 29, 35, 40, 41 and 46, Balat discloses a system comprising a lead (Fig. 1) with a lumen (unlabelled lumen containing the fixation member), an intraluminal anchoring device (5a), a polymeric tether detachably connected to the anchor, extending proximally from the anchor through the lumen of the lead (unlabelled member between 5a and 5b, col. 4, line 45), the anchor is disposed distally of the lead (Fig. 2), and the lead is longitudinally movable with respect to the anchor (Figs. 1 and 2). Furthermore, Balat's invention is capable of introduction into "a coronary lumen" because the size of the lumen has not been set forth, and because Balat's invention is inserted into the heart and is of a similar size to a coronary lumen. Alternatively, it is well known in the art to provide anchored leads in the coronary lumens to provide therapy to the left heart and to stabilize the lead. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Balat's lead in a coronary lumen to provide therapy to the left heart and stabilize the lead.

7. In regards to claims 30, 36 and 42, the system comprises a connector for limiting longitudinal movement between the lead and the anchoring device (5b).

8. In regards to claims 31 and 37, the tether is non-electrically conductive (col. 4, line 41). The specified materials are non-conductive.

9. In regards to claims 34 and 43, the anchor comprises a self-expanding structure (the "harpoon" structure will expand to at least its state in Fig. 1 after passing through the smaller diameter region of "1b" due to the resilient nature of the anchor material).

10. In regards to claims 47-49, the lead is an implantable pacing lead (col. 1, line 5). Because this lead is implanted in a cavity of the heart, it is capable of providing pacing therapy.

11. In regards to claims 32, 38 and 44, Although Balat further discloses that the tether may be comprised of a twisted material (col. 4, line 43), Balat does not disclose that the tether is braided. It is well known in the art to provide braided structures in leads to provide both strength and flexibility. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Balat's invention by providing a braided tether to provide both strength and flexibility.

Response to Arguments

12. Applicant's arguments with respect to claims 29-32, 34-38 and 40-49 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bardy et al. (US 5,231,996) is one of many references that teach providing a lead with a braid and Chastain et al. (US 6,178,356) is one of many references that teach of providing a lead to a coronary lumen.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWK

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GEORGE R. EVANISKO
PRIMARY EXAMINER

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